**Fenofibrate 200mg capsules**

- You have an under active thyroid gland (hypothyroidism)
- You have diabetes, especially Type 2 diabetes, that is not well controlled
- You have problems with certain proteins in your blood
- You have an alcohol problem
- You are taking other medicines
- You or your family have had muscle problems
- You are over 70 years of age

(Some of these above conditions can lead to high levels of lipids in your blood and need to be corrected before you start therapy with fenofibrate).

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Fenofibrate capsules.

Your doctor might want to test your blood or urine to check if Fenofibrate capsules are working properly and also if your kidneys, muscles and liver are working properly.

**Effects on muscles**

Stop taking Fenofibrate capsules and see a doctor straight away if you get unexplained muscle pain, tenderness or weakness.

This can cause muscle breakdown and exercise, weight loss, to lower levels of fats in the blood. Fenofibrate 200mg capsules can be used in addition to other medicines (statins) in some circumstances when levels of fats in the blood are not controlled with a statin alone.

**What is in this leaflet**

1. What Fenofibrate capsules are and what they are used for
2. What you need to know before you take Fenofibrate capsules
3. How to take Fenofibrate capsules
4. Possible side effects
5. How to store Fenofibrate capsules
6. Contents of the pack and other information

**What Fenofibrate capsules are and what they are used for**

Fenofibrate belongs to a group of medicines, commonly known as fibrates. These medicines are used to lower the level of fats (lipids) in the blood. Fenofibrate 200mg capsules are used, alongside a low fat diet and other non-medical treatments such as exercise and weight loss, to lower levels of fats in the blood.

Fenofibrate belongs to a group of medicines, commonly known as fibrates. These medicines are used to lower the level of fats (lipids) in the blood.

Fenofibrate 200mg capsules can be used in addition to other medicines (statins) in some circumstances when levels of fats in the blood are not controlled with a statin alone.

**What you need to know before you take Fenofibrate capsules**

Do not take Fenofibrate capsules and tell your doctor if:

- You are allergic to fenofibrate or any of the other ingredients of this medicine (listed in section 4).
- While taking other medicines, you have had an allergic reaction or skin damage from sunlight or UV light. (These medicines include other fibrates and an anti-inflammatory medicine called 'non-steroidal anti-inflammatory drugs').
- You have never had liver, kidney or gallbladder problems.
- You have pancreatitis (an inflammation of your pancreas) which causes abdominal pain, which is not caused by high levels of fat in the blood.

Do not take Fenofibrate capsules if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Fenofibrate capsules.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Fenofibrate capsules if:

- You have an liver or kidney problems
- You have kidney disease
- You may have an inflamed liver (hepatitis) – signs include yellowing of the skin and whites of the eyes (jaundice) and an increase in liver enzymes (shown in blood tests).

**How to take Fenofibrate capsules**

It is important to take the capsule with food – it will not work as well if your stomach is empty.

Take Fenofibrate capsules every day at the same time of day with food.

**Possible side effects**

- These problems are rare but include muscle inflammation and breakdown. This can cause kidney damage or even death.
- Your doctor may do a blood test to check your muscles before and after starting treatment.

**Effects on muscles**

The risk of muscle breakdown is higher in some patients. Tell your doctor if:

- You are over 70 years old
- You have kidney problems
- You have thyroid problems
- You or a close family member has a muscle problem which runs in the family
- You drink large amounts of alcohol
- You are taking medicines called statins to lower cholesterol – such as simvastatin, atorvastatin, pravastatin, rosuvastatin or fluvastatin.
- You have ever had muscle problems during treatment with statins or fibrates such as fenofibrate, bezafibrate or gemfibrozil.

If any of the above apply to you (or you are not sure), talk to your doctor before taking Fenofibrate capsules.

**Interactions**

Tell your doctor or pharmacist if you are taking any other medicines.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- Anti-cancer medicines to treat your blood (such as warfarin).
- Other medicines to control fat levels in the blood (such as statins or fibrates).
- Taking a statin at the same time as Fenofibrate capsules may increase the risk of muscle problems.
- A particular class of medicines to treat diabetes (such as sitagliptin or pioglitazone).
- This can cause kidney damage or even death.

Your doctor may do a blood test to check your muscles before and after starting treatment.

**Other medicines and Fenofibrate capsules**

Tell your doctor or pharmacist if you are taking the following medicines:

- You have ever had muscle problems during treatment with statins or fibrates such as fenofibrate, bezafibrate or gemfibrozil.

If any of the above apply to you (or you are not sure), talk to your doctor before taking Fenofibrate capsules.

**Fenofibrate capsules with food, drink and alcohol**

It is important to take the capsule with food – it will not work as well if your stomach is empty.

**In particular tell your doctor or pharmacist if you are taking any of the following medicines:
- You have ever had muscle problems during treatment with statins or fibrates such as fenofibrate, bezafibrate or gemfibrozil.

If any of the above apply to you (or you are not sure), talk to your doctor before taking Fenofibrate capsules.
Fenofibrate 200mg 28 Capsules PIL - UK

**Pregnancy, breast-feeding and fertility**
- Do not take Fenofibrate capsules and tell your doctor if you are pregnant or planning to have a baby.
- Do not take Fenofibrate capsules if you are breast-feeding or planning to breast-feed your baby.
- Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**
This medicine will not affect you being able to drive or use tools or machines.

**Fenofibrate capsules contain lactose**
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product, as it contains a type of sugar called lactose.

**Fenofibrate capsules contain Ponceau 4R, cochineal red A (E124)**
Fenofibrate capsules contain Ponceau 4R, cochineal red A (E124) which may cause allergic reactions.

### How to take Fenofibrate capsules
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

**Taking this medicine**
- Swallow the capsule whole with a glass of water
- Do not open or chew the capsule
- Take the capsule with food — it will not work as well if your stomach is empty

**How much to take**
The recommended dose for adults is one capsule a day, taken at mealtimes.

**Use in children and adolescents**
The use of Fenofibrate 200mg capsules is not recommended in children under the age of 18.

**People with kidney problems**
If you have kidney problems, your doctor may tell you to take a lower dose. Ask your doctor or pharmacist about this.

**If you take more Fenofibrate capsules than you should**
If you take more Fenofibrate capsules than you should, or if someone else has taken your medicine, contact your nearest hospital casualty department or tell your doctor immediately.

**If you forget to take Fenofibrate capsules**
- If you forget a dose, take the next dose with your next meal
- Do not take a double dose to make up for a forgotten dose
- If you are worried about this talk to your doctor.

**If you do not take Fenofibrate capsules**
Do not stop taking Fenofibrate capsules unless your doctor tells you to, or the capsules make you feel unwell. This is because abnormal levels of fat in the blood need treating for a long period of time.

Remember that as well as taking Fenofibrate capsules it is important that you:
- Have a low fat diet
- Take regular exercise
- If you have any further questions on the use of this product, ask your doctor or pharmacist.

### Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Stop taking Fenofibrate capsules and tell your doctor immediately if you develop:**
- Muscle poisoning: muscle pain, breakdown, inflammation, cramps or weakness, increase in the levels of a certain enzyme within the body (seen in a blood test).
- Contact your doctor immediately if you develop:
- An allergic reaction: swelling of the face, lips, tongue or throat, itchy skin rash, narrowing of the airways causing difficulty breathing or swallowing.
- Hepatitis: yellowing of the skin or whites of the eyes (jaundice), itching.
- Tell your doctor if you notice any of the following side effects or notice any other effects not listed.

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### Fenofibrate Capsules

**Fenofibrate 200mg 28 Capsules PIL - UK**

**Item no:** BBBA0075

**Contents of the pack and other information**

**What Fenofibrate capsules contain**
- The active substance (the ingredient that makes the capsules work) is micronised fenofibrate. Each capsule contains 200mg of the active substance.
- The other ingredients are lactose monohydrate, pregelatinised starch, sodium lauryl sulphate, pectin, magnesium stearate, gelatin, titanium dioxide (E171), yellow iron oxide (E172), ponceau 4R, cochineal red A (E124).

**What Fenofibrate capsules look like and contents of the pack**
Fenofibrate capsules are orange, hard, gelatine capsules. Pack size is 28.

**Marketing Authorisation Holder and Manufacturer**
Actavis, Barnstaple, EX32 8NS, UK.

The leaflet was last revised in March 2019.

### If you would like a leaflet with larger text, please contact

01271 385257.

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